

### **REMARKS**

Claims 1-57 and 60-71 are pending in the current application. Claims 58 and 59 have been cancelled, without prejudice to, or disclaimer of the subject matter therein.

### **ELECTION/RESTRICTION**

A requirement for restriction has been made under 37 C.F.R. 1.499 between the inventions of Groups:

- I. Claims 1-19 and 45-47, and 51-55 drawn to an immunogenic composition.
- II. Claims 20-44 drawn to an isolated immunogenic composition comprising an outer membrane vesicle preparation.
- III. Claims 56-57 drawn to a method of treatment or prevention of Gram negative bacterial disease.
- IV. Claims 58-59, 61, 64, and 65 drawn to a use in the preparation of a medicament, a method of making the immunogenic composition, and a method of making the vaccine (Examiner interprets the use claim as a method of use in the preparation of a medicament).
- V. Claim 60 drawn to a genetically engineered Gram negative bacterial strain from which the outer membrane vesicles within the immunogenic composition can be derived.
- VI. Claims 62-63 drawn to a method of making the immunogenic composition comprising a step of isolating outer membrane vesicles from a Gram negative bacterial culture.
- VII. Claim 66 drawn to a method of preparing an immune globulin.
- VIII. Claims 67-68 drawn to an immune globulin preparation.
- IX. Claim 69 drawn to a pharmaceutical preparation comprising monoclonal antibodies.
- X. Claim 70 drawn to a method of treatment or prevention of Gram negative bacteria infection.

- XI. Claim 71 drawn to a use of the pharmaceutical preparation in the manufacture of a medicament for the treatment or prevention of Gram negative bacterial disease (Examiner interprets the use claim as a method of use in the pharmaceutical preparation in the manufacture of a medicament for the treatment or prevention of Gram negative bacterial disease).
- XII. Claims 48-50 drawn to an immunogenic composition comprising one or more polynucleotide(s) encoding a transferrin binding protein or antigenic fragment thereof.

Applicants elect **Group I** with traverse.

The Examiner alleges that the inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: (i) The technical feature of Group I is an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. (ii) The technical feature of Group I lacks an inventive step over Hermand et al WO 02/30458A1. (iii) Hermand et al teaches an immunogenic composition comprising an isolated transferrin binding protein (Tbp) and an isolated Hsf like protein from the same or different Gram negative bacteria (see abstract and pgs. 1-5 and 13-16).

Applicants respectfully traverse that the claimed subject matter lacks inventive step over Hermand et al. Applicants' representative has diligently reviewed Hermand et al. and cannot determine where it discloses an immunogenic composition comprising an isolated transferrin binding protein (Tbp) and an isolated Hsf like protein from the same or different Gram negative bacteria. Rather, Hermand et al. relates to adjuvant compositions that comprise a Yersinia adhesion protein which are suitable to be used in vaccines and further provides vaccines comprising the adjuvants and an antigen or an antigenic composition. (for example, abstract; page 1, lines 1-13; page 8, lines 17-21). On pages 12-19 Hermand et al. list viruses, bacteria, and

parasites from which an antigen or antigenic composition may be derived and numerous examples of antigens, any one of which may be chosen. Applicants respectfully submit that the technical feature of Group I is not disclosed in Hermand et al. Therefore, Applicants' respectfully traverse that Group I lacks unity with Groups II-XII.

Election of Species:

The Office Action also requires election of species of the generic invention. If the Applicants elect Group I or Group II, they are also required to elect a combination of a single individual species from Species I, Species II, and Species III for Group I and II listed below.

Species I-Transferrin Binding Protein;

- A) *Neisseria*;
- B) *Moraxella catarrhalis*;
- C) *Haemophilus Influenzae*;

Species II-Hsf like Protein;

- A) *Neisseria*;
- B) *Moraxella catarrhalis*;
- C) *Haemophilus Influenzae*;

Species III- Polysaccharide;

- A) *Neisseria*;
- B) *Haemophilus influenzae* B;
- C) *Streptococcus pneumoniae*, Group A *Streptococci*, and Group B *Streptococci*;
- D) *Staphylococcus aureus* and *Staphylococcus epidermidis*;

Applicants elect the following species for purposes of initial examination on the merits: **Species I: A) *Neisseria*, Species II: A) *Neisseria*, Species III) *Neisseria*.**

Claims 1-19, 45-47 and 51-55 are within elected Group I; claims 1-8, 13-19, 45-47 and 51-55 read on the elected species.

In the event that one or more generic claims are found to be allowable, Applicants respectfully request examination of additional species which are dependent from or otherwise include all the limitations of the allowable generic claims as required under 37 C.F.R. 1.141.

Applicants also note that the subject matter of Group I, Group III, and Claims 61, 64 and 65 of Group IV, are related to each other as product and process of making and using the product. When product claims (for example, one or more of Claims 1-19, 45-47 and/or 51-55) are found to be allowable, Applicants respectfully request rejoinder of process claims that are dependent or otherwise include all the limitations of the allowed product claims as required by MPEP § 821.04(b).

Applicants expressly reserve the right to prosecute the subject matter in the non-elected claims, originally filed claims, or any other claims supported by the specification in one or more continuing applications.

### **CONCLUSION**

Applicants elect Group I with traverse (Claims 1-19, 45-47 and 51-55) and further elect the following species: Species I: A) Neisseria, Species II: A) Neisseria, Species III) Neisseria.

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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